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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,271	07/23/2003	Terry R. Hobbs	58017US002	8409

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EXAMINER	
PAK, JOHN D	

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/625,271

Applicant(s)

HOBBS ET AL.

Examiner

JOHN PAK

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2007 and 09 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-11,13,14,16 and 24-38 is/are pending in the application.
- 4a) Of the above claim(s) 28-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-11,13,14,16,24-27,37 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/07</u> . | 6) <input type="checkbox"/> Other: _____ |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/27/2007 (which is a request to enter the after-final amendment of 3/28/2007) has been entered.

Claims 1-2, 5-11, 13-14, 16 and 24-38 are pending in this application. The restriction requirement and applicant's election continue to apply in this RCE. Accordingly, claims 28-36 stand withdrawn as being directed to non-elected subject matter. Claims 1-2, 5-11, 13-14, 16, 24-27 and 37-38 will presently be examined.

Applicant is advised that should claim 16 be found allowable, claim 27 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 8, 13 and 24 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Independent claim 1 has been amended so that the aromatic acid component comprises an acid and a salt. Claim 8 sets forth the aromatic acid component in a Markush language but the Markush group does not include a salt. Claim 8 is therefore improperly dependent on claim 1.

Claims 13 and 24 share the same problem in that they are not properly dependent from claim 1. Claim 1 has set forth the solvent in a closed Markush group. The solvents of claims 13 and 24 are not included in the Markush group of claim 1. Claims 13 and 24 are therefore improperly dependent on claim 1.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 5-11, 13-14, 16, 24-27 and 37-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 has been amended so that the composition consists essentially of several components, wherein "a solvent is selected from the group consisting of amine oxides, phenol ethoxylates, fatty acid amides, sorbitan esters, fatty alcohol ethoxylates, block copolymers of ethylene oxide and propylene oxide and combinations of the foregoing" (emphasis added).

Original disclosure stated that these ingredients are surfactants. See original claim 12 and specification page 10, first full paragraph.

The claimed surfactant amount is 5 wt% or less. However, the solvent amount disclosed in the specification can be as high as 40 wt% (page 9, first full paragraph).

Therefore, characterizing amine oxides, phenol ethoxylates, fatty acid amides, sorbitan esters, fatty alcohol ethoxylates, block copolymers of ethylene oxide and propylene oxide and combinations thereof as solvents changes their composition percentages.

Lack of adequate descriptive support is thus found in two respects. First, the fact that these ingredients are to be used as solvents means that the originally disclosed solvents are not being picked as solvents when a solvent is used. Second, the wt% of the solvent is not the same as the wt% of the surfactant, so characterizing the ingredients of claim 1 as solvents introduces new subject matter, i.e. new wt% for the ingredients. For these reasons, the claims are found as lacking in adequate descriptive support from the originally filed disclosure.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5-10, 13-14, 16, 26-27, 37-38 stand/are rejected under 35 U.S.C. 102(b) as being anticipated by Devillez (US 5,736,582) for the reasons of record.

Devillez explicitly discloses a skin treating composition that contains, inter alia, the following ingredients at pH 4.6:

3.5 wt% hydrogen peroxide (calculated from 10% of a 35% solution);

1 wt% salicylic acid;

1.67 wt% cetyl alcohol;

74.8 wt% distilled water;

0.3 wt% sodium hydroxide;

0.06 wt% simethicone (has antifoam properties);

0.31 wt% sodium lauryl sulfate;

1.86 wt% Promulgen G (stearyl alcohol + cetareth-20, which is a fatty alcohol ethoxylate).

See column 6, lines 45-56 and column 7, lines 28-30.

Claim 1 requires both an aromatic acid and a salt of the aromatic acid. It is noted that Devillez's composition has sodium hydroxide added to it, q.s. pH 4.6. Sodium hydroxide would then necessarily react to produce the salt form of the acid and render some salt form to be present in the composition. See for example applicant's agreement on this point (in situ salt) in the instant specification, page 9, lines 1-3.

The kill rate feature in claim 2 is noted, but such feature is deemed to be an inherent characteristic of Devillez's composition that contains the same exact ingredients as applicant's composition. Additionally, such kill rate can depend on the challenge level and the particular bacteria strain. As a result, when the Examiner can show a prior art composition that contains the same ingredients as the claimed invention, the burden of showing that the prior art composition does not somehow have the same properties shifts to applicant. MPEP 2112, 2112.01.

Claim 26 requires the composition to be more resistant to catalase deactivation than an aqueous solution of hydrogen peroxide. The Examiner's position is that since Devillez's composition contains the same ingredients as applicant's composition, the same resistance must necessarily be present.

Method of claim 37 is noted but such method would necessarily have been obtained from Devillez's teachings since the ingredients must be combined in order to obtain the mixture of ingredients. All other claim features are plainly encompassed by Devillez's composition, as shown above.

Applicant's comments filed with the RCE (which is a request for consideration of arguments of 3/28/2007) have been given due consideration but they were deemed unpersuasive. Claim 11 is not included in this ground of rejection, so reliance on this point is not understood. Claim 12 (canceled) was somewhat distortedly incorporated into the current version of claim 1 (see the preceding new matter discussion), but it must be noted that Devillez's composition contains cetareth-20, which is an ethoxylated fatty alcohol. Hence, the subject matter of original claim 12, as well as the subject matter of instant claims, is anticipated by Devillez.

Claims 1-2, 5-10, 13-14, 16, 24-27 and 37-38 stand rejected under 35 U.S.C. 102(b) as being anticipated by Devillez (US 5,958,984).

Devillez explicitly discloses a skin treating composition that contains the following ingredients at pH 4.6:

- 3.5 wt% hydrogen peroxide (calculated from 10% of a 35% solution);
- 1 wt% salicylic acid;
- 10 wt% propylene glycol;
- 1.6 wt% cetyl alcohol;
- 74 wt% distilled water;
- 0.3 wt% sodium hydroxide;
- 1.8 wt% Promulgen G (stearyl alcohol + cetareth-20);

0.06 wt% simethicone; and

0.3 wt% sodium lauryl sulfate.

See the paragraph bridging columns 6-7 and the "ACNE SKIN TREATMENT COMPOSITION."

Claim 1 requires both an aromatic acid and a salt of the aromatic acid. It is noted that Devillez's composition has sodium hydroxide added to it, q.s. pH 4.6. Sodium hydroxide would then necessarily produce the salt form of the acid and render some salt form to be present in the composition. See for example applicant's agreement on this point (in situ salt) in the instant specification, page 9, lines 1-3.

The kill rate feature in claim 2 is noted, but such feature is deemed to be an inherent characteristic of Devillez's composition that contains the same exact ingredients as applicant's composition. Additionally, such kill rate can depend on the challenge level and the particular bacteria strain. As a result, when the Examiner can show a prior art composition that contains the same ingredients as the claimed invention, the burden of showing that the prior art composition does not somehow have the same properties shifts to applicant. MPEP 2112, 2112.01.

Claim 26 requires the composition to be more resistant to catalase deactivation than an aqueous solution of hydrogen peroxide. The Examiner's position is that since Devillez's composition contains the same ingredients as applicant's composition, the same resistance must necessarily be present.

Method of claim 37 is noted but such method would necessarily have been obtained from Devillez's teachings since the ingredients must be combined in order to obtain the mixture of ingredients. Applicant's "consisting essentially of" language has been discussed in previous Office actions (e.g. see pages 4-6 of the 12/28/2006 Office action), and the discussion there is incorporated herein by reference. The ingredients of the cited prior art composition E would not be excluded by the claim language for the reasons stated above. All other claim features are plainly encompassed by Devillez's composition, as shown above.

Applicant's comments filed with the RCE (which is a request for consideration of arguments of 3/28/2007) have been given due consideration but they were deemed unpersuasive. Claim 11 is not included in this ground of rejection, so reliance on this point is not understood. Claim 12 (canceled) was somewhat distortedly incorporated into the current version of claim 1 (see the preceding new matter discussion), but it must be noted that Devillez's composition contains cetareth-20, which is an ethoxylated fatty alcohol. Hence, the subject matter of original claim 12, as well as the subject matter of instant claims, is anticipated by Devillez.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 5-11, 13-14, 16, 24-27 and 37-38 are rejected under 35 U.S.C.

103(a) as being unpatentable over Del Duca et al. (EP 916721).

Del Duca et al. disclose a 0.1-20 wt% or 2-10 wt% hydrogen peroxide composition that contains a buffering system, which includes 0.1-10 wt% or 0.3-2 wt% benzoic acid/sodium benzoate, phthalic acid/potassium phthalate, or salicylic acid/sodium salicylate (paragraphs 13, 20, 21, 30 & claims 1, 5-6).

Del Duca et al. teach incorporation of surfactants, solvents and various other ingredients (paragraph 50). Surfactants can be incorporated at 0.5-15 wt% or 1-10 wt% (paragraph 52). Suitable surfactants include fatty alcohol ethoxylates (see the formula in paragraph 55; see also paragraph 57), fatty acid amides (paragraph 60), amine oxides (paragraph 65), and diesters of sulfosuccinate, especially saturated C₆₋₁₄ diesters (page 9, lines 45-46). pH of up to 7 is disclosed for the composition (claim 1). Water as a major component in the composition is disclosed (see all the examples).

The percentage range and component selection as claimed are fairly suggested by Del Duca et al. Even though fatty alcohol ethoxylates, fatty acid amides, amine oxides and C₆₋₁₄ diesters of sulfosuccinate are not designated as "solvent," inclusion of such ingredients is taught. Motivation to select the specific fatty alcohol ethoxylates, fatty acid amides, amine oxides and/or C₆₋₁₄ diesters of sulfosuccinate arises from their being taught as being suitable and stable to hydrogen peroxide (paragraph 51).

Claim 2 recites a pathogenic bacteria kill rate of 99.9% in about 90 seconds. Identification of bacteria or pathogen load is not provided. Therefore, one having ordinary skill in the art would have fairly expected such kill rate depending on the bacteria, bacterial viability/vigor/susceptibility, and bacterial load from a composition that contains the level of hydrogen peroxide as taught by Del Duca et al.

Claim 6 requires that the aromatic acid component is present in a concentration sufficient to provide synergy with hydrogen peroxide to kill microorganisms. Del Duca et al. provide the same hydrogen peroxide and the same aromatic acid + salt combination, wherein the same surfactant, solvent and carrier are suggested. Thus, the same property would be possessed by Del Duca's aromatic acid component + hydrogen peroxide.

Claims 13 and 24 require solvents, which are selected from a list that includes ethanol and isopropanol. Given the various formulation adjuvants disclosed by Del Duca et al., in view of the teaching of solvents (paragraph 50), common solvents such as ethanol and isopropanol would have been an obvious inclusion, particularly for improving the mixing and formulating of the composition. 1-40 wt% of solvents such as those recited in applicant's claim 24 is fairly suggested by the expected solvent function of ethanol and isopropanol. Adjustment of quantity for formulation homogenization and/or optimization would have been within the skill of the ordinary skilled artisan.

Claim 14 recites an emulsion with water carrier. Del Duca's majority water + surface active ingredient-containing examples are fairly suggestive of water based emulsions.

Claims 16 and 27 recite pH of 3.5-5. Del Duca's pH ranges up to 7, and all the examples have the pH's between 4-5. Such disclosure taken with the buffering capacity of benzoic acid/sodium benzoate, phthalic acid/potassium phthalate, or salicylic acid/sodium salicylate (paragraph 29) suggests applicant's claimed feature.

Claim 37 merely requires combining the initial components. Del Duca's disclosure is suggestive of the same (see above citations).

Claim 38 requires the composition of claim 1 to be formulated for application to skin. Such language is broad in that virtually any scope can be encompassed. Formulated for application to skin can mean formulated for cauterization or rapid and indiscriminate disinfection for emergency infections. Ingredients used by Del Duca et al. are the same as those used by applicant. The ingredients are not inherently toxic to the skin. Del Duca's composition is deemed to be within the language of claim 38.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited reference.

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With respect to this ground of rejection, applicant's specification data has been reviewed for objective evidence of nonobviousness. The following comments explain why they are not probative evidence of nonobviousness.

Example	Comments
1	- Does not have the "solvent" as defined in independent claim 1. - Even if claim 1 were amended to fit this example, the data (using sodium dioctyl sulfosuccinate, benzoic/benzoate) is nowhere commensurate in scope with that of the entire claimed subject matter.
2	- Does not contain mixture of aromatic acid and aromatic acid salt.
3	- See comments for Example 1
4	- Does not contain mixture of aromatic acid and aromatic acid salt.
5	- This is not a comparison against the closest prior art. Naked hydrogen peroxide is not the closest prior art formulation of hydrogen peroxide.
6	" "
7	" "
8	" "
9	- See comments for Example 1. Also, the comparison Example B cannot be compared because too many variables are different between Example 9 and Example B.
10	- Does not have the "solvent" as defined in independent claim 1. - Even if claim 1 were amended to fit this example, the data (using sodium lauryl sulfate, benzoic/benzoate) is nowhere commensurate in scope with that of the entire claimed subject matter.
11	" "

For these reasons, the claims must be rejected.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 5-11, 13-16, 24-27, 37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of copending Application No. 11/153,760. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The copending claims recite the following ingredients in a mycobactericidal composition:

- synergistic combination of 1-70 wt% alcohols such as ethanol and n-propanol with 0.03-5 wt% benzoic acid (claims 1-3, 9);
- less than 1 wt% of a surfactant such as amine oxides, block copolymers of ethylene oxide and propylene oxide, sodium dioctyl sulfosuccinate (claims 12, 15-17);
- and

- up to 10 wt% of hydrogen peroxide (claims 21-22).

pH of the composition is about 3.5-6.5 (claim 25).

Although a salt of an aromatic acid is not expressly disclosed by the copending claims, presence of some amount of the salt form in equilibrium would have been obvious, particularly in view of the moderate pH range of the copending composition.

The percentage range and component selection as claimed in this application are fairly suggested by the copending claims.

Claim 2 recites a pathogenic bacteria kill rate of 99.9% in about 90 seconds. Identification of bacteria or pathogen load is not provided. Therefore, one having ordinary skill in the art would have fairly expected such kill rate depending on the bacteria, bacterial viability/vigor/susceptibility, and bacterial load from a composition that contains up to 10 wt% hydrogen peroxide + synergistic mixture of alcohol and benzoic acid.

Claim 6 requires that the aromatic acid component is present in a concentration sufficient to provide synergy with hydrogen peroxide to kill microorganisms. The copending composition would have been expected to provide synergistic activity, and since the components are the same, the same activity would have been possessed by the copending composition.

Claim 14 recites an emulsion with water carrier. Given all the surfactants and additives, use of water for its common carrier/solvent functionality and emulsion

resulting from water + surfactants would have been obvious to the ordinary skilled artisan.

Claim 37 merely requires combining the initial components. Copending claims are suggestive of the same since mixing of starting ingredients is obvious.

Therefore, the claimed invention, as a whole, would have

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's new IDS is noted and U.S. Patent 6,294,186 is noted in particular. Teachings of this patent is similar to the two patents by Devillez, supra, in that hydrogen peroxide + aromatic acid (plus in situ salt form) are present together in a composition along with many other formulation additives such as the ingredients of applicant's invention (see in the 6,294,186 patent, Examples 34-35). Since the ground of rejection over this patent would be substantially the same as the two already of record over Devillez's patents, another ground will not be added here based on the current claims.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is (571)272-0620. The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



John Pak
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